

(19) World Intellectual Property Organization
International Bureau



10/517809
13 DEC 2004

(43) International Publication Date
4 September 2003 (04.09.2003)

PCT

(10) International Publication Number
WO 03/072025 A2

- (51) International Patent Classification⁷: **A61K** (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (21) International Application Number: PCT/US03/04866
- (22) International Filing Date: 21 February 2003 (21.02.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/357,851 21 February 2002 (21.02.2002) US
- (71) Applicant (*for all designated States except US*): **BIOVAIL LABORATORIES INC.** [BB/BB]; Chelston Park, Building 1, Ground Floor, Collymore Rock, St. Michael, West Indies (BB).
- (72) Inventors; and
- (75) Inventors/Applicants (*for US only*): **SETH, Pawan** [IN/US]; 10 Meryton, Irvine, CA 92612 (US). **MAES, Paul, J.** [BE/US]; 10205 Windsor View Drive, Potomac, MD 20854 (US).
- (74) Agents: **TESKIN, Robin, L.** et al.; Pillsbury Winthrop LLP, 1600 Tysons Boulevard, McLean, VI 22102 (US).
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— *without international search report and to be republished upon receipt of that report*
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: MODIFIED RELEASE FORMULATIONS OF AT LEAST ONE FORM OF TRAMADOL

(57) Abstract: The present invention provides for a modified release pharmaceutical composition comprising at least one form of tramadol selected from the group consisting of tramadol, enantiomers thereof, pharmaceutically acceptable salts thereof and combinations thereof, the composition exhibiting an *in vitro* dissolution profile (measured using the USP Basket Method at 75 rpm in 900 ml 0.1 N HCl at 37 °C) such that after 2 hours, from about 0 % up to about 30 % (by weight) of the at least one form of tramadol is released, after 4 hours, from about 5 % to about 22 % (by weight) of the at least one form of tramadol is released, after 6 hours, from about 15 % to about 38 % (by weight) of the at least one form of tramadol is released, after 8 hours, more than about 40 % (by weight) of the at least one form of tramadol is released.

WO 03/072025 A2